SMARxTFILLER™ ®

Syringe Filling System

Model: 1366-2018

OPERATOR'S MANUAL

Smartfiller® Legal Notices

Manufacturer Warranty

Seller warrants equipment of its own manufacture to be free from defects in materials and workmanship for ***one (1)*** year from date of shipment under normal usage (one shift per day basis), if such defect is not caused by normal wear, negligence or abuse by Purchaser. No warranty or guarantee can be made for rubber or plastic belts, wheels or parts. This warranty extends only to the original Purchaser and is limited to repair or replacement (at Seller's option), FOB Seller's factory, or any original part or component manufactured by Seller, which is found by Seller to have been defective at time of shipment, provided written claim has been received from shipment and such original part of component is returned prepaid to Seller. With respect to equipment, materials, parts, and accessories manufactured by others: Seller will undertake to obtain from Purchaser the full benefit of manufacturer's warranties. Seller shall not be held responsible for loss of products, loss of production time or any contingent losses due to such defects, and all claims for such contingent losses are expressly waived by Purchaser. **THIS WARRANTY IS IN LIEU OF ANY OTHER WARRANTIES, EXPRESS, IMPLIED, OR STATUTORY.**

Disclaimer

No responsibility is assumed by the manufacturer for any injury and/or damage to persons or property as a result of the use or operation in a manner not specified in the manual. All responsibility is waived when the user is negligent to any warnings and cautions specified in the manual and/or labels on the Smartfiller® unit

Training Advisory

THIS MANUAL IS INTENED TO BE USED AS A GUIDE ONLY.

User must receive proper on-site training and an understanding of the facilities standard operating procedures/guidelines prior to operating the Smartfiller®. This will ensure that the unit is being operated in a safe and aseptic manner.

European Supplier Information:

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Basic	
Name	Smartfiller®
Model	1366-2018
Function	Syringe Filling System
IP Rating	IP20
Operating Noise Level	<70 db @ 1 m
Electrical	
Volts:	200-230V
Hz:	50/60
Watts:	100 (MAX)
Fuse:	2A F, 250V
Physical Attributes	
Weight	94 lbs (42.6 kg)
Dimensions (L x W x H)	32.75in **x** 10.75in **x** 23in (83.19cm **x** 27.31cm **x** 58.4cm)
Operating Environment	
Environment:	In-door Use ONLY!
Temperature:	Ambient Room Temp 64.4°F - 95°F (18°C – 35°C)
Humidity:	20-80 % (Non-Condensing)
Altitude (Max):	6000 ft (1828 m)

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CHAPTER 1-INTRODUCTION

- ABOUT THE USER MANUAL
- SYSTEM DESCRIPTION
- SYSTEM CHARACTERISTICS & FEATURES
- PRODUCTS HANDLED

About the User Guide

This manual will contain information and directions that will guide the user through all phases of using the Smartfiller® from installation to filling syringes. Any user operating the Smartfiller® must read and understand all directions and warnings within the manual prior to use. The sole purpose and intention of this manual is to ensure the operator receives a complete understanding of the components and proper operating instructions. Listed below are the major sections that the manual is divided into:

1. Introduction
2. Safety and Warnings
3. Unpacking & Installation
4. Identifying System Components
5. Understanding System Controls
6. Setup
7. Running the System
8. Changeover
9. System Maintenance
10. Bill of Materials

Notes for This Manual

Throughout the manual you will find various notes and warnings depicted in bold or specially marked for your benefit. These warnings and notes are categorized is various levels of importance and it is highly recommended that the user pay extra close attention to these sections of the manuals.

WARNING!

Information related to the warning is pertinent to both the user and system for safe operation. Disregarding the warning could result in serious personal injury or system damage.

NOTE!

Information related to the note is important and should be taken into serious consideration when operating the system.

[START]

Text that is displayed in bold and surrounded by brackets indicates a button on the touchscreen display.

About the Smartfiller®

The Smartfiller is a fully automated syringe filling system designed to fill syringes in a laminar airflow environment. The Smartfiller® meets the growing worldwide demand for pre-filled syringes in hospitals. Compared to the manual filling of syringes in the ward or the pharmacy of a hospital, the automatic filling of syringes with the help of Smartfiller® results in better quality compounded IV-drugs and labor conditions.

Characteristics of the Smartfiller®

- *Fills syringes from 1 ml to 60 ml*
- *Fills up to 360 syringes per hour. (Output varies depending upon system parameters.)*
- *Can be changed over to a different size syringe in less than 15 minutes*
- *Is specially designed to operate under laminar flow conditions*
- *Uses disposable syringes, tip caps, filling tubes, and connectors*
- *Is equipped with autoclavable machine parts*
- *Has a technical life span of 10 years*
- *Has a 1-year warranty on the full performance of the machine*

Process Description

The *Smartfiller*® is designed to remove the tip cap, fill syringe to desired volume, and then re-apply the tip cap. This model fills syringes by drawing material from a hanging IV bag. Liquid is drawn from the IV bag by a fill arm that lifts up on the syringe plunger. The fluid is drawn into the syringe using the suction generated by drawing the plunger upward. The tubing setup in between the IV bag and fill adaptor, is normally pinched off by a pinch valve. This prevents the bag from empting its contents when syringes are not filling. This method eliminates any hazards or contamination that would normally be caused by the use of a pump. The operator loads syringes into the in-feed track, which feeds the syringes to the starwheel. The starwheel is then indexed until the cap sensor sees a syringe tip cap. In the fill station, the plunger end is aligned inside the fill arm and the syringe is in place for cap removal and filling. The cap/fill tool then rotates underneath of the cap and rises to a predetermined height, pressing the cap onto the syringe tip. This ensures that all caps are pressed on to the same position. The cap/fill tool will then remove the tip cap. Once the cap is removed the cap/fill tool rotates and attaches the fill adapter to the syringe tip creating a tight seal. The syringe is now ready to fill. The pinch valve will now open, as the fill arm rises, pulling the plunger in a vertical motion, drawing fluid to the preselected volume. The pinch valve then closes, clamping off the tubing and the fill arm will stop, or continue to rise to create suck back. The fill adaptor is then removed from the syringe tip. The tip cap is now placed back onto the syringe. The starwheel then indexes and repeats the process over again.

CHAPTER 2 – SAFETY & WARNINGS

- **INTRODUCTION**
- **SAFETY WARNINGS**
- **SYMBOL & TERM CHART**

Smartfiller® Safety and Warnings

The operator's manual and Smartfiller unit contain symbols and warnings designed to prevent injury or hazard toward the user. This section of the manual will help define the symbols that that you will come across when reading this manual or operating the Smartfiller®. Ignoring the below symbols or warnings could result in machine malfunction, serious injury or even death.

NOTE!

Please read all instructions prior to installing or operating the system. Operation and Installation instructions are designed for user safety to prevent serious personal injury.

Installation

- **DO NOT** install the Smartfiller® near any flammable substances. Contact between flammable substances and the machine can potentially lead to fire or possible electrical shock.
- **DO NOT** install the Smartfiller® in a location where water or liquids could possibly come in contact with the machine. This could result in fire or possible electrical shock.
- **DO NOT** install the Smartfiller® near extreme high or low temperatures. Effects of extreme temperature may lead to fire or possible electrical shock.
- **DO NOT** install the Smartfiller® on an unleveled surface. Machine could possibly slide or move causing injury to the operator.
- **DO NOT** install the Smartfiller® in a location where items have the potential of falling or striking the machine or the operator.
- **DO NOT** install the Smartfiller® in an area without adequate light. Operating the Smartfiller® in dark areas or areas without sufficient light may lead to serious personal injury.

Electrical

- Power Cord is to be plugged **ONLY** in to a properly ground receptacle. Failure to do so could result in possible electrical shock.
- **DO NOT** intentionally damage or modify the power cord. Power cord included with the machine is designed to meet electrical specifications for the Smartfiller® unit. Alterations to the power cord may lead to fire or possible electrical shock.
- **DO NOT** plug power cord into a multi-plug power strip or extension cords. This may cause fire or electrical shock.
- **DO NOT** expose electrical cord to water, sharp edges, or moving parts that could potentially cause damage to cord. This may cause fire or possible electrical shock.

- **DO NOT** Exposing the electrical cord to extreme heat or cold increases decay in wiring and may lead to damage to the cord. This may potentially cause fire or electrical shock.
- Prior to connecting electrical cord inspect for exposed wiring and frays in the wire. A damaged electrical cord could lead to possible fire or electrical shock.
- **DO NOT** plug power cord into a receptacle that is not easily accessible. In the event of an emergency this may cause a delay in disconnecting unit from power source.

Handling

- **DO NOT** remove any of the covers from the Smartfiller®. The machine contains high voltage components that may cause fire or electrical shock if handled.
- **DO NOT** attempt to make mechanical or electrical alterations to the Smartfiller®. Doing so may cause fire or electrical shock.
- **DO NOT** leave machine powered on for long durations of time when machine is not being used. Turn power off and disconnect power cord when it's known that the machine will not be used for several days.

Maintenance

- Turn power OFF and disconnect power cord prior to any routine maintenance or cleaning of the Smartfiller®. Failure to do may cause fire or electrical shock.
- **DO NOT** use aerosol sprays, water, soap or other cleaning agents directly on Smartfiller®. When cleaning the Smartfiller® apply the cleaning agent to a soft cloth, mildly dampening the cloth

Lifting

- Machine is **HEAVY**. Use (2) people when moving the Smartfiller® as well as proper lifting techniques. Failure to do so may cause personal injury.
    - When lifting the Smartfiller®, lift only by the base.

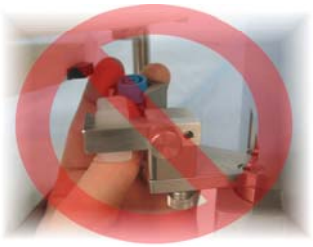
Personal Safety

- When operating the Smartfiller® **BE ALERT** at all times. Lack of attention can lead to mistakes and possible serious injury.
- Avoid wearing loose clothing or jewelry when using the Smartfiller®. Clothing and jewelry can easily become caught in moving parts of the machine.

Pinch Hazards

The Smartfiller® unit contains several Pinch Hazards. Refer to below notes and pictures to help identify all possible hazards. Failure to observe and stay clear of these areas may cause serious personal injury.

PINCH POINTS CAN CAUSE SERIOUS AND PERMANENT INJURIES. PLEASE FOLLOW ALL INSTRUCTIONS WHEN WORKING IN THESE AREAS OF THE MACHINE.



Safety Symbol and Term Chart

Warning Symbol or Term	Definition
	Warning: When symbol is followed by a WARNING term this indicates that the practice or operation being performed can possibly cause death or serious injury if directions are not followed correctly. Pay close attention and use extreme caution when performing duties or operations associated with the warning symbol and term
	Caution: When symbol is followed by a CAUTION this indicated that the practice or operation being performed may cause injury to operator or possible damage to the Smartfiller® unit if directions are not followed correctly. Pay close attention and use extreme caution when performing duties or operations associated with the CAUTION symbol and term.
	This symbolizes that there is potential electrical hazard. Use extreme caution; disregard of electrical hazards could cause fire or possible electrocution.
	This symbolizes that there is a specific pinch hazard associated with the operation being described. When symbol is located on the machine this indicates that moving parts present possible pinch hazards. Refer to safety section of manual for description of pinch hazards associated with the Smartfiller®.
I	This symbolizes Power ON. When this side of the power switch is depressed it is indicating that the machine is in the ON position.
O	This symbolizes Power OFF. When this side of the power switch is depressed it is indicating that the machine is in the OFF position.
	This symbolizes earth ground.

CHAPTER 3-UNPACKING & INSTALLATION

- Unpacking
- Transporting
- Installing

Introduction

This Section of the operators guide will help guide you through installing your Smartfiller®. It is important to remember when moving the Smartfiller® to always use assistance and carry Smartfiller® by the base ONLY! Other areas of the Smartfiller® are not designed as lifting points and may bend, flex, or break due to lifting from that point.

Prior to installing or removing the Smartfiller® from its packaging a location meeting the system requirements should be determined. Some of the factors that should be taken into consideration when installing the unit are adequate spacing, system weight, and power requirements. All system requirements can be located in the beginning of this guide under System Requirements.

Smartfiller® Installation Requirements:

- Dry Environment (Smartfiller® is not susceptible to water. Contact with water will lead to machine malfunction.)
- Clean area free of any debris
- Smartfiller® requires adequate spacing. This will allows the user to place other necessary materials required for syringe filling in close proximity of the unit. These materials may include such items as IV Stand for the IV bag of product and collection bin for filled syringes.
- 115/230 VAC Proper Earth/Ground Connection
- Level Surface

Recommended Area Dimensions:

- *Height – 24" **minimum***
- *Width- 44" **minimum***
- *Depth- 20" **minimum***

Crate Contents:

- *Operator's Manual*
- *Syringe Catch Bin*
- *Smartfiller®*
- *IEC Power Cord (US/EU)*
- *Changeparts (Optional)*

Unpacking

The Smartfiller is packaged in a custom pallet crate to provide protection to the Smartfiller and ensure safe delivery to the customer location. This section of the manual is intended to provide the user with directions to properly remove the unit from its pallet. It is recommended that the pallet and crate be saved for any necessary future transportation.

Recommended Items to Unpack Smartfiller®

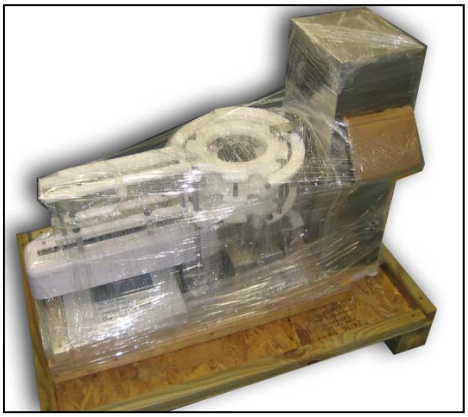
- Cordless Drill
- #2 Phillips Drill Bit

Instructions to remove the Smartfiller® from the Shipping Crate:

1. Using a cordless drill remove all the screws around the bottom perimeter of the crate.

2. After the screws have been removed, using assistance lift the crate away from the pallet. The crate cover will be required to be lifted at least 3’ in height from the base to clear the top of the Smartfiller unit.

3. Place the crate cover in a safe place for future use.



4. Remove the plastic wrap from the Smartfiller. DO NOT USE knife or razor blade to remove plastic, which may cause damage to the machine.

5. Using a cordless drill remove the (2) wooden cross members that tie the unit to the base. Save these pieces for future use.
   Refer to *Figure 3-05.*

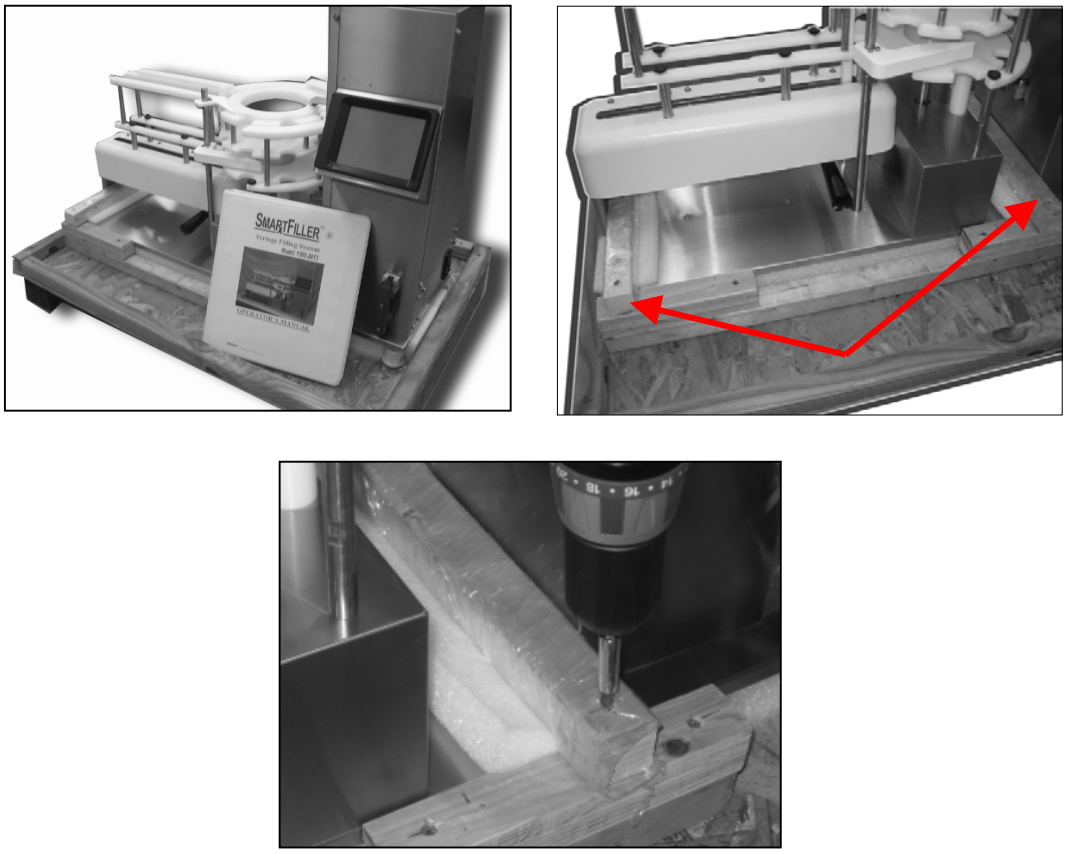
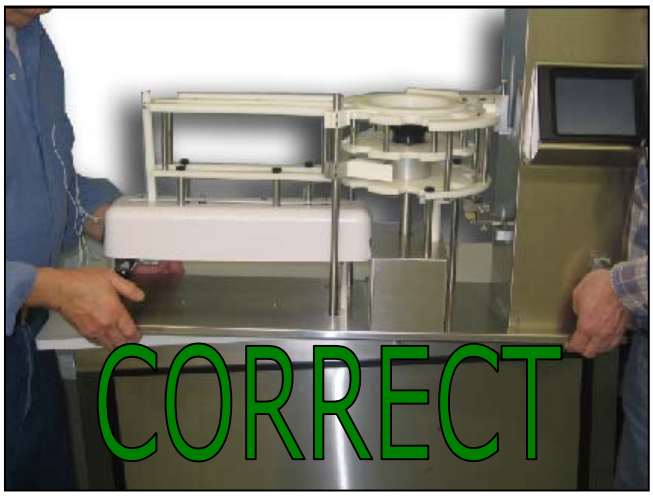


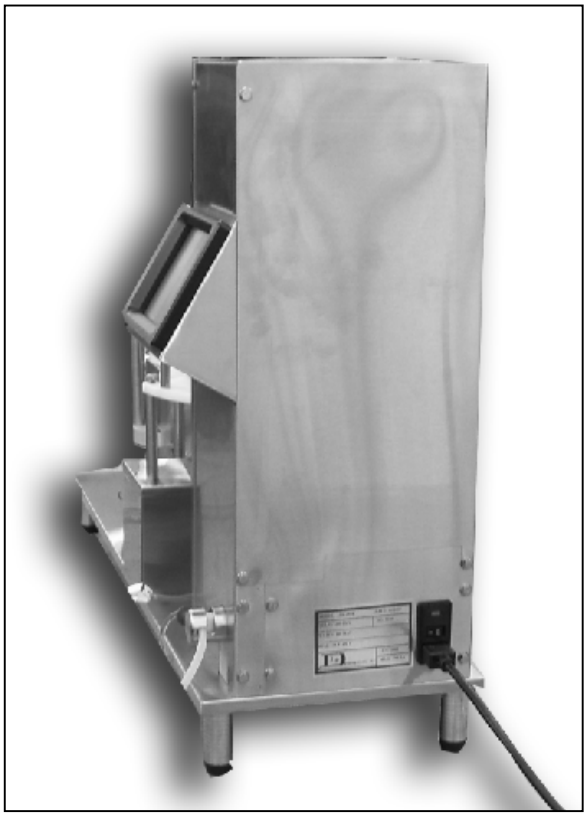
Figure 3-05

Transporting

When transporting the Smartfiller all users should use proper lifting techniques to reduce any risk of injury or damage to the machine. When moving the Smartfiller (2) personnel should move the unit lifting by the base only. Lifting the Smartfiller by areas or components other then the base could result in damage to the machine or personal injury.



Installing



1. Locate a clean and aseptic area in which the Smartfiller® can be placed for operation. Typically the Smartfiller® will be placed under a laminar hood in an aseptic environment.

2. Place the Smartfiller® in the selected area that the machine is going to be used.

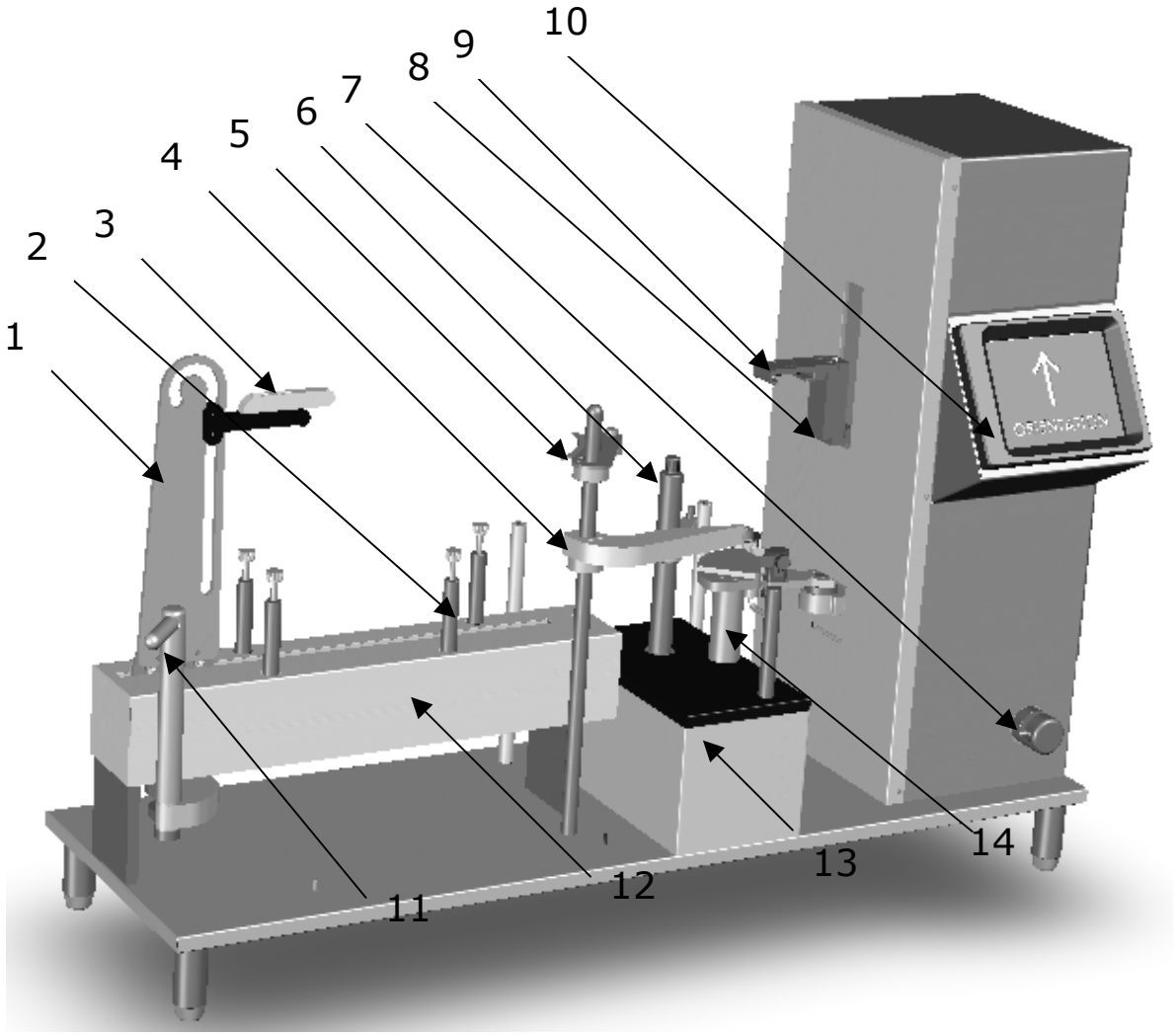
3. Check and make sure that the Power On/Off Switch is in the OFF position. On/Off switch is located on the right side of the machine when facing the Touchscreen display.

4. Take the 6 ft power cord supplied with the Smartfiller® and attach the IEC/IBM to connection on the side of the unit.

5. Connect the male end of the power cord to a 115/230 VAC proper earth/ground connection.

CHAPTER 4 – IDENTIFYING SYSTEM COMPONENTS

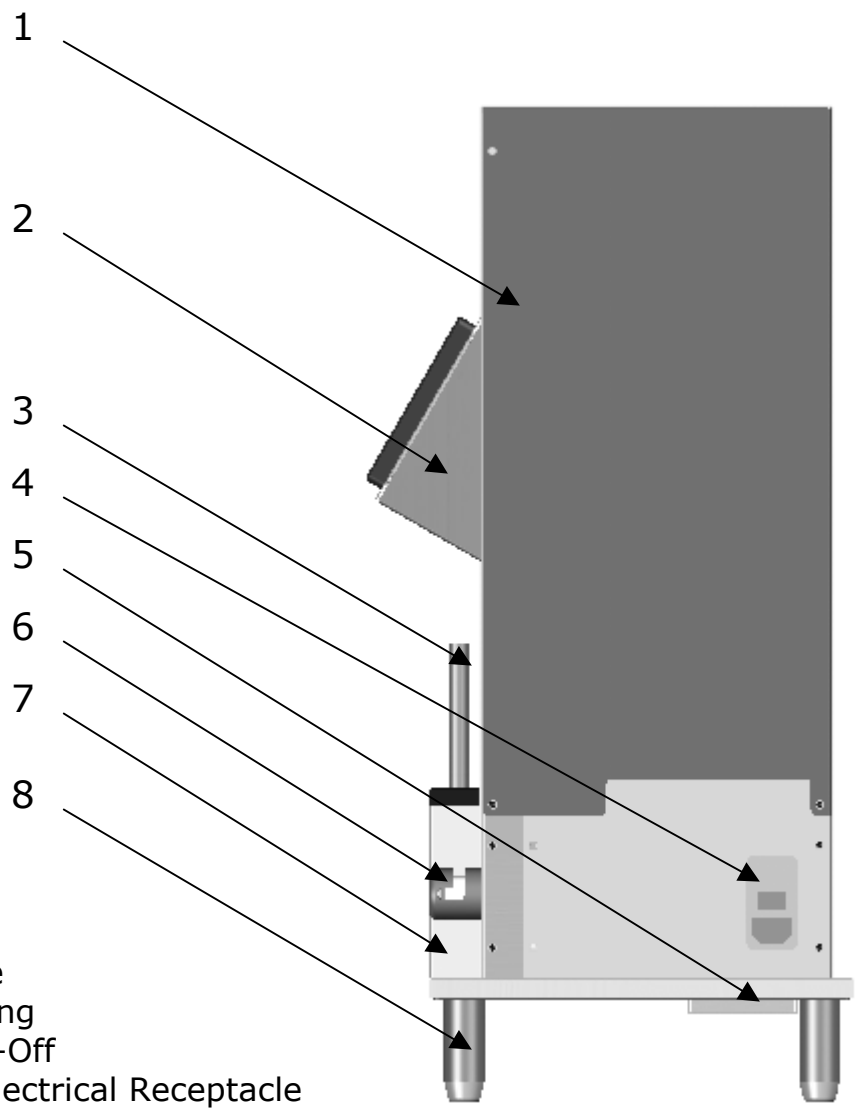
Smartfiller Model 1366-2018



Base Unit

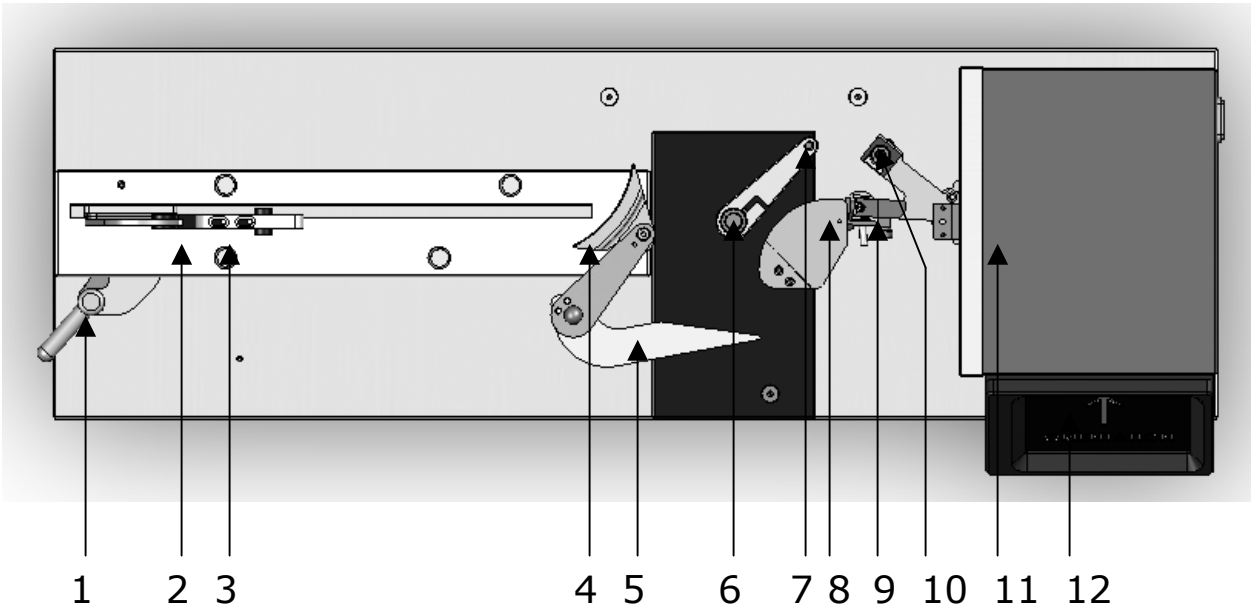
1. Syringe Pusher
2. Infeed Guide Stand-Off
3. Small Syringe Feeder Extension
4. Outfeed Stripper Wedge
5. Flange Stripper
6. Filling Starwheel Drive Shaft
7. Pinch Housing
8. Syringe Grabber Extension Arm
9. Syringe Grabber Finger
10. Touchscreen
11. Slide Handle
12. Infeed Cover
13. Starwheel Drive Cover
14. Syringe Present Sensor Mount Side View

Side View



1. Electrical Enclosure
2. Touchscreen Housing
3. Outer Guide Stand-Off
4. ON/OFF Switch / Electrical Receptacle
5. Wire Cover
6. Pinch Housing
7. Starwheel Drive Cover
8. Base Leg

Overhead View



1. Slide Handle
2. Infeed Cover
3. Infeed Stand-Off
4. Flange Stripper
5. Outfeed Stripper Wedge
6. Starwheel Drive Shaft
7. Starwheel Arm
8. Syringe Present Sensor Housing
9. Luer Block
10. Tip Cap Removal Block
11. Electrical Enclosure
12. Touchscreen

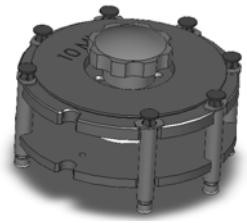
Change Parts

The Smartfiller unit requires assorted change parts in order to run various syringe sizes. The Smartfiller® is capable of running the following BD® syringes in both Europe and North American markets (60mL, 30mL, 20mL, 10mL, 5mL, 3mL, & 1mL).

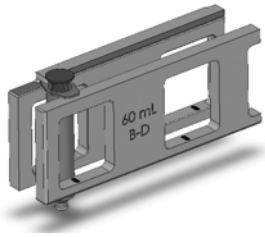
NOTE! –

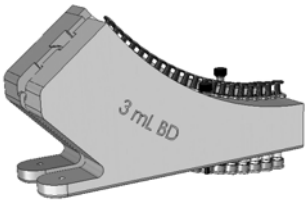
Change Parts may appear different then those represented below and are subject to change without notice.

Starwheel(s)



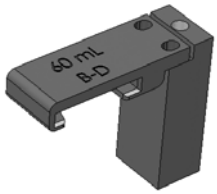
Infeed Guide Rails

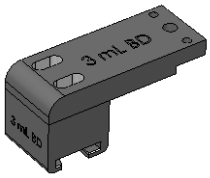




Outer Guide Rail

Gripper Finger





* Parts depicted above are subject to change without notice.

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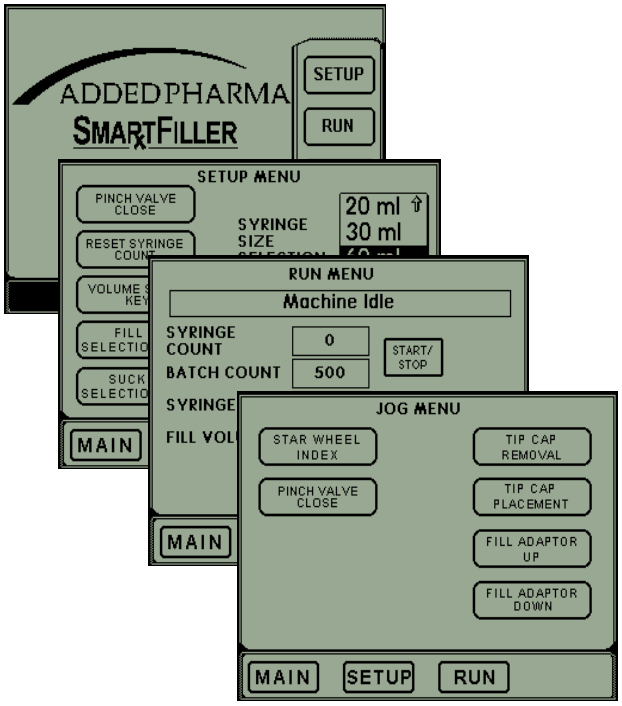
CHAPTER 5 – UNDERSTANDING SYSTEM CONTROLS

- *Overall Touchscreen*
- *Main Menu*
- *Setup Menu*
- *Jog Menu*
- *Run Menu*

Introduction

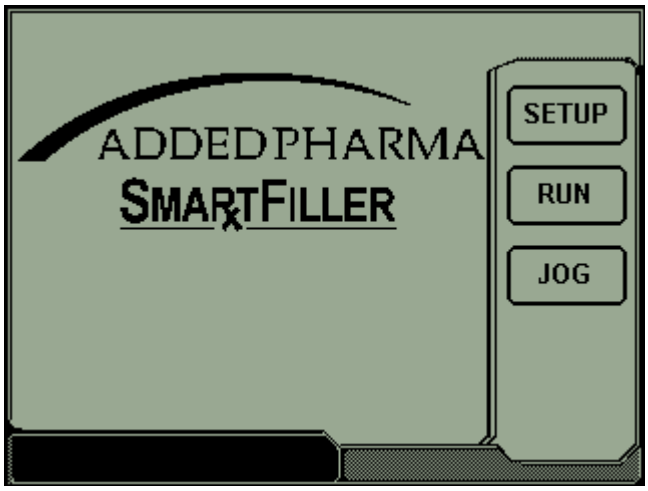


The Smartfiller® units are programmed prior to shipment but do require additional set-up before running the unit. The software allows the user to make several adjustments such as, fill volume, syringe size, syringe count, and batch counters. These adjustments are made using the LCD touch screen display on the front of the machine. The touch screen acts as both an interface between the Smartfiller® software and as a display. This section of the manual will help you become familiar with the touch screen and its multiple menus. The touch screen is only accessible when the machine is powered on. Please read entire operational manual prior to exploring the touch screen.

The Smartfiller® Touch screen contains several layers of screens that can be accessed though buttons on the screen. Once the machine is powered on it will display the Main Menu or may be referred to as the Start-Up screen. This screen contains three buttons that will link to the four other sub-screens utilized for operation of the machine. These menus are the Setup, Run, and Jog Menus. On the following pages there are detailed descriptions of each of these menus and their functions as well as the Main Menu.

Description of Main Menu

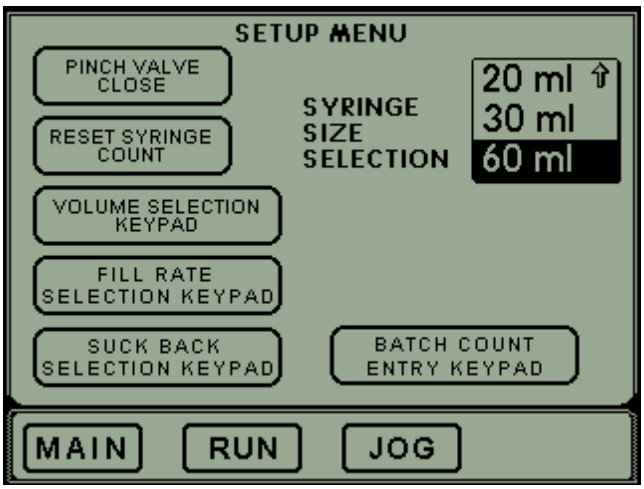
The ***Main Menu*** screen is used to select the desired sub screen for setup, data collection or machine operation. When the ***Main*** is touched on any sub-screen, the touch screen returns to this screen. When the desired sub-screen is touched, the touch screen will shift to that screen.



Button / Display	Description & Function
SETUP	When pressed changes the screen to the Setup Menu
RUN	When pressed changes the screen to the Run Menu. * If the system setup has not been configured the screen will automatically be re-directed to the Setup Menu.
JOG	When pressed changes the screen to the Jog Menu.

Description of the Setup Menu

The Setup Menu is used to configure all system parameters prior to filling syringes. Accessing the SETUP Menu can be done by pressing [SETUP] at the bottom portion of the menu. The Setup Menu allows the user to load/unload the tubing set, configure batch counts, speeds, and syringe size and volume selection.

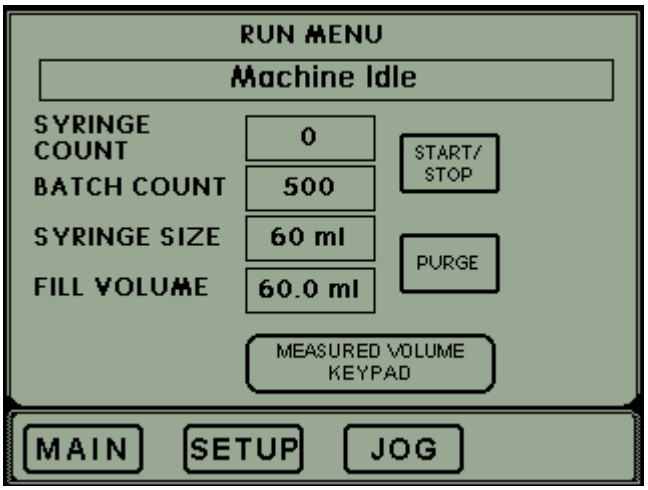


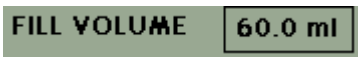
Button / Display	Description & Function
	This button opens and closes the pinch valve to load tubing. The button will be displayed either open or close depending on the position of the pinch valve. If the valve is open the button will be displayed as Pinch Valve Close. If valve is closed the button will read Pinch Valve Open. Pressing the button will carry out the command stated on the button.
	Pressing this button will reset the syringe count to 0000.
	Pressing this button will bring up a numeric keypad. Using the keypad the user can select the fill volume up to 60mL. The minimum volume will vary depending on the syringe size selected. *The operator must enter 3 digits. For example 20.0 would be entered as 2, 0, and 0. The decimal point is automatically entered. Prior to entering the desired volume press the clear button followed by the 3 digits. Then press set. This will enter the desired volume into machine memory.
	Pressing the button will bring up a numeric keypad in which the fill rate can be selected. The keypad will only accept a fill rate between 01-18. If entering a new fill rate press the clear button followed by entering the desired value and set button.
	Pressing this button will bring up a numeric keypad. This will control how much air is drawn into the syringe following the fill. This adjustment is used to eliminate drip when the fill adaptor is pulled away from the syringe tip. To enter a new value press clear and enter the new value followed by the set button. It is recommend to start with a suck back value of 02.
	Pressing this button will bring up a numeric keypad. This is used to set the desired batch count. When entering the desired batch count, a four-digit number must be entered even if the batch count is only to be 10. The operator must enter 10 as 0010.

Button / Display	Description & Function
	When pressed changes the screen to the Main Menu.
	When pressed changes the screen to the Run Menu.
	When pressed changes the screen to the Jog Menu.
	The highlighted syringe size is the syringe size selected. Using your finger or stylus move the highlight bar up and down for the desired syringe size. There are currently 8 syringe sizes to choose from ranging from 01mL to 60mL. On the top of the Starwheel there will be a syringe size stamped in to the surface. Refer to that size when selecting the syringe size in the setup menu. Both of these sizes must match for proper machine function.

Description of the Run Menu

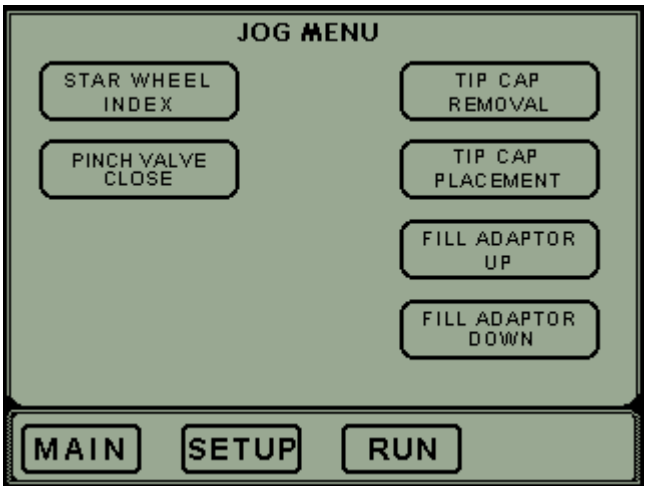
The Run Menu is used when the Smartfiller System is filling syringes. This is the menu that will be utilized to start and stop the syringe filling process. Within this menu the operator may view various parameters and access the Measured Volume Keypad to offset syringe fill volumes.



Button / Display	Description & Function
	Pressing this button on the touch screen is pressed when the machine is idle it starts the machine cycle. If the button is pressed while the machine is running a message STOP PENDING is displayed to the right of the button. This indicates the machine will stop once the syringe fill cycle is complete.
	Pressing this button will empty the Starwheel of any syringes.
	Pressing the button will bring up a numeric keypad that is to be used following the initial run of new product. Additional information regarding the measured volume can be found in the Smartfiller® setup section of the manual.
	This window on the touch screen displays the current number of syringes filled on the system.
	This window on the touch screen displays the selected batch count.
	This window on the touch screen displays the syringe size
	This window displays the selected fill volume for the syringes.
	When pressed changes the screen to the Main Menu.
	When pressed changes the screen to the Setup Menu.
	When pressed changes the screen to the Jog Menu.

Description of the Jog Menu

The Jog Menu is used for system setup and analyzing machine performance. It is suggested that personnel who have be fully trained on the functions of this menu utilize this screen. Within this menu the operator may jog various system components independently of the machine filling cycle.



Button / Display	Description & Function
STAR WHEEL INDEX	This button advances the Starwheel to the next position. This function is used if the machine has been powered down and the Starwheel may have drifted from its home position. This button can also be used if attempting to send the unit through all of the motions of filling a syringe. Pressing the button will rotate the next syringe in place for cap removal and filling.
PINCH VALVE CLOSE	This button when pressed will open the Pinch Valve. This window is only displayed when the Pinch Valve is closed.
TIP CAP REMOVAL	This button will send the machine through the motions of pressing the tip cap on to the desired height and then removing the tip cap off of the syringe. The syringe is now ready for attachment of the fill adaptor.
TIP CAP PLACEMENT	This button can only be selected if the REMOVE TIP CAP button was previously selected. This will place the tip cap back onto the syringe.
FILL ADAPTOR UP	This button can only be selected if the REMOVE TIP CAP button was previously selected. This will rotate the fill adaptor to line up with the syringe tip. The fill adaptor will then rise attaching the fill adaptor to the syringe.
FILL ADAPTOR DOWN	This button can only be selected if the REMOVE TIP CAP button was previously selected. This will rotate the fill adaptor to line up with the syringe tip. The fill adaptor will then rise attaching the fill adaptor to the syringe.
MAIN	When pressed changes the screen to the Main Menu.
SETUP	When pressed changes the screen to the Setup Menu.
RUN	When pressed changes the screen to the Run Menu.

DESCRIPTION OF SCREEN MESSAGES

The following messages will be displayed on the touch screen. These messages are prioritized so that if two (2) conditions exist the higher priority will be displayed.

Status Messages

MACHINE RUNNING- This message will be displayed when the machine is running normally.

MACHINE IDLE- This message will be displayed when the machine is in the run menu and the machine is not running.

Error Messages

Luer Motor Error- This message will be displayed if the luer cannot reach its home or working position.

Remove Tip Cap - This message will be displayed following any Luer Motor Errors. The message is displayed telling the operator to remove the tip cap from the holder so that the machine can continue the filling process.

Star Motor Error- The message will be displayed if the Star Wheel is unable to advance entirely to its home position.

Pinch motor error- The message will be displayed if the Pinch Valve does not open or close completely.

Rotate Motor Error- This message will be displayed if the tip cap removal block or the luer block is unable to rotate in the desired position.

Fill Motor Error- This message will be displayed if the fill arm is unable to reach its home position following a fill.

CHAPTER 6– SYSTEM SETUP

- **Software Setup**
- **Load IV Tubing and Set-Up**
- **Loading Syringes**
- **Measured Volume**

Preparing the Smartfiller® for Running

The following section of the manual will cover four phases of preparing the Smartfiller® for operation.

- Become familiar with Smartfiller® components and Touch screen menus.
- Using the Touchscreen SETUP menu make the necessary adjustments in order for desired machine function
- Load IV Tubing and Set-Up
- Loading Syringes
- Measured Volume

Exploring Touchscreen Menus

Prior to using a machine the user should always make themselves familiar with the machine they are about to operate. Using the Smartfiller® Component (pg. 10) section of the manual attempt to identify the various machine components and their potential hazards. Smartfiller® Software and LCD Touch Screen s (pg. 12-15) sections of the manual can be used to help navigate though the multiple Touchscreen menus. Understanding how the machine properly functions will make the rest of machine setup easier.

Software Set-Up

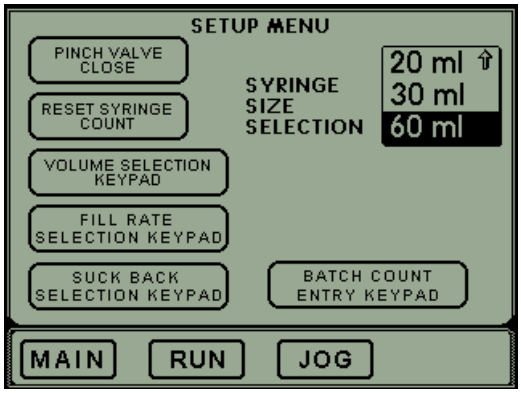
Prior to running the Smartfiller the operator must complete setting all system parameters. This section of the manual is intended to help guide you through the various parameters and how to properly set each of them.

With the system in place & installation complete turn the power switch to the on position.

✋WARNING!

Keep Hands clear of system when turning power on. System will undergo a homing sequence upon powering which will cause parts and components to move automatically without notice.

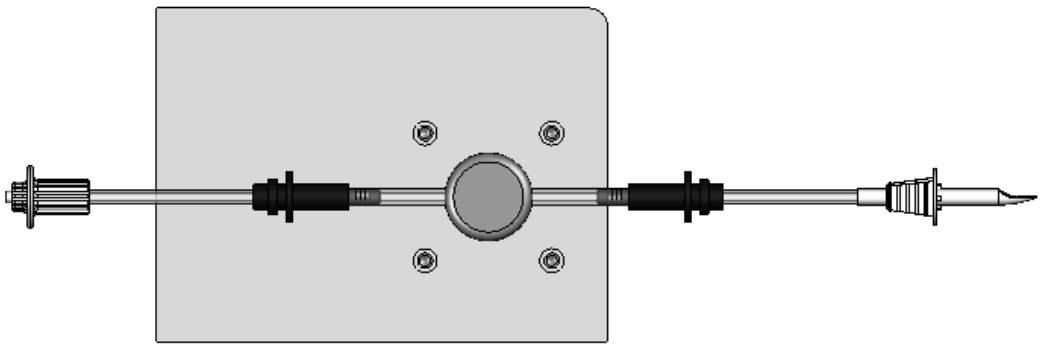
Press [**SETUP**] located on the right hand side of the main screen to display the SETUP Menu.



Loading IV tubing Set

Press [**Pinch Valve Load**] to open the pinch valve.

Insert the tubing set so that the Luer-loc connection is to the left of the pinch valve and the IV-Bag spike is to the right. (Refer to diagram below).



Press [**Pinch Valve Close**]

Selecting Syringe Size & Volume

Prior to running the Smartfiller the syringe size and volume desired must be selected. The software that controls the unit will not allow the operator access to the run screen until these parameters are set.

Located in the upper-right corner of the SETUP menu is the Syringe Size Selection window. The syringe size must be selected prior to entering the syringe volume.

Press the **[⇧ ⇩]** arrows within the window to scroll thru the selections.

Once the desired size is visible press the syringe size to highlight the selection.

Press [**VOLUME SELECTION KEYPAD**] to enter the desired fill volume. This will display a keypad menu to enter the volume.

NOTE!

Must enter 3 digits for volume. The decimal point will be automatically inserted.

Ex. 9.5 mL would be entered as 0, 9, 5.

Press [**SET**]. (Refer to Table 6-1 for Fill Volume Limits).

Syringe Size	Minimum Fill Volume	Maximum Fill Volume
1 mL	00.1 mL	01.0 mL
3 mL	00.3 mL	03.0 mL
5 mL	00.5 mL	05.0 mL
10 mL	01.0 mL	10.0 mL
20 mL	04.0 mL	20.0 mL
30 mL	10.0 mL	30.0 mL
60 mL	10.0 mL	60.0 mL

Fill Rate

The fill rate ranges from a setting of 0-18. The purpose of this setting is to allow the Smartfiller to achieve the optimal output of syringes per minute. This setting requires adjustment depending on the sizes of the syringe as well as the product viscosity.

Press [**FILL RATE SELECTION KEYPAD**] to display the numeric entry keypad.
Enter the desired fill rate.
Press [**SET**]

NOTE!

Fill Rate Speed will cause variation in the syringe output per minute. Running at higher rates then intended will result in inaccurate fill volumes.

Suck Back

The Suck Back setting is intended to eliminate any drip when filling syringes with product with low viscosity. The suck back setting when utilized will cause the Smartfiller® to pull slightly up on the plunger after detaching the luer to prevent product from dripping from the tip of the syringe. The suck back setting may range from 0-10, ten being being the maximum suck back. To adjust the suck back setting follow the instructions below.

1. Press [**SUCK BACK ENTRY KEYPAD**]

2. Enter desired suck back setting.

3. Press [**SET**] on the keypad to enter load the value and return to the SETUP Menu.

Batch Count

The Batch Count can be set from 0001-9999 syringes. The batch count will stop the system once the unit has filled the desired number of syringes.

1. Press [**BATCH COUNT ENTRY KEYPAD**] to display the numeric entry keypad.

2. Enter the desired batch count using the keypad.

3. Press [**SET**] to load the value and return to the SETUP Menu.

Once all parameters have been entered the message appearing on the setup menu "Must set parameters" will be removed and the operator then may enter the run menu.

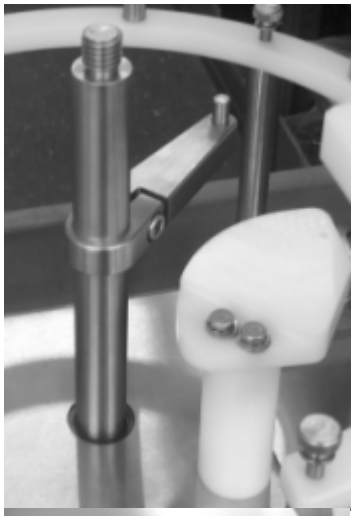
Installing Change Parts

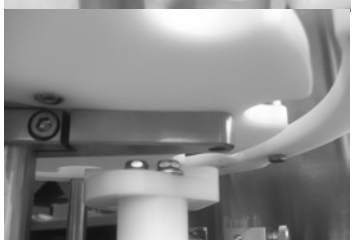
When setting the Smartfiller up to run a batch of syringes the correct change parts must be installed. The change parts will vary in size, design, and components depending on the type and size of the syringe being ran. The change parts will usually consist of a Starwheel, Infeed Rails, Outer Guide Rail, and possible gripper finger and extension. Change parts are intended to be quick, easy, and require little use of hand tools to change.

Materials Needed:

(7) Thumb Knobs

Attaching Components.

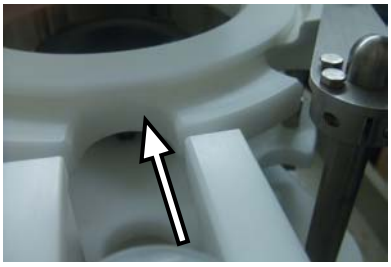




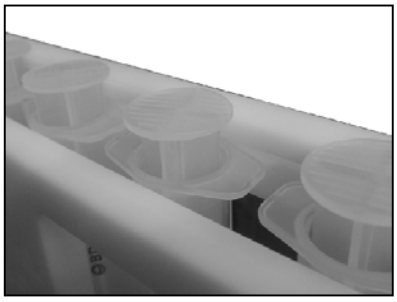
1. Gather all the change parts required for the desired size that will be used.
2. Place the Starwheel onto the Main Drive Shaft.
3. Place the Outer Guide Rail onto the posts and secure using (3) thumbscrews.
4. Place the Infeed Rails onto the Stand-Off Posts and secure using the (4) thumbscrews.
5. Align the hole on the Bottom of the Starwheel with the pin on the Starwheel Locator Arm.
6. Secure the Starwheel with the Starwheel Knob.
7. Attach the Gripper Finger and secure with thumbscrew. (The gripper finger may be a (2) piece assembly depending on the syringe size. Some size change parts require that the gripper finger also have an extension block.)
8. Slide the Stripper Finger back onto its post. Position the Stripper Finger up against the Starwheel and tighten the thumb knob.
9. Re-Position the Stripper Wedge so that syringes will be fed away from the Starwheel after being filled. When positioning the wedge make sure that the wedge will not force the syringe up against the Syringe Outer Guide Assembly.

Aligning Infeed Rails

After all the change parts are placed onto the base unit and secured the Infeed Rails must be aligned in order for syringes to feed properly into the Starwheel.



1. Turn the unit power on.
2. Press [**JOG**] on the Main Menu to go to the Jog screen.
3. Press [**STARWHEEL INDEX**] twice to jog the Starwheel (2) indexes.
4. Loosen the thumbscrews that attach the Infeed rails to their standoff posts.
5. Place the syringes in the guide rails keeping the push bar pulled back.
6. Align the inside guide rails with the Starwheel and tighten the screws.

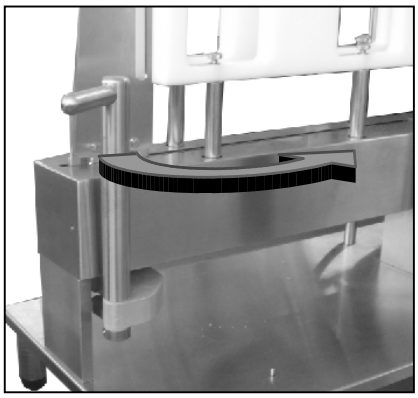


7. Make the back guide rail parallel with the front so that all the syringes are held between the (2) rails.
8. Turn the syringes 90° and check that the syringes can move freely through the rails without falling though.
9. After ensuring that the rails are aligned appropriately load the Infeed with syringes and release syringe pusher.
10. Using the Jog Menu index the syringes though the Starwheel to make sure all syringes index without issue.

Loading the Smartfiller

When loading syringes in between the Smartfiller® guide rails care should be taken to avoid possible machine jams or errors. Do not attempt to overload the guide rails with syringes.

1) Pull the *Syringe Push Bar* handle away from the Star Wheel.
   - The Push Bar consist of a magnetic catch witch will lock the push bar in place to allow for loading.
2) Insert one Syringe in opening of guide rails farthest from the star wheel.
   - When inserting syringe place syringe so that the syringe barrel flanges rest on each of the guide rails.
3) Slide syringe towards star wheel.
   - Continue loading syringes in between guide rails until you have loaded desired amount.
4) Twist the Syringe Pusher Handle to release the Syringe Pusher.



NOTE!

DO NOT ATTEMPT TO OVERLOAD THE GUIDERAILS. DEPENDING ON THE SIZE OF THE SYRINGE THE AMOUNT OF SYRINGES THAT MAY BE LOADED WILL VARY

Measured Volume

The measured volume is designed to add additional accuracy to the fill volumes. Because the Smartfiller® will be used to handle a wide range of products fill volumes may vary. The measured volume offsets the initial fill volumes so that syringes are filled to the desired measurement. This part of the set-up is to be done just prior to filling syringes and must be done with the product that the syringe will be filled with.

Setting the Measured Volume

1) Set the Smartfiller® up for running the machine follow all SETUP instructions as well as RUN instructions.
2) Load the Smartfiller® with syringes.
3) Run the Smartfiller®
4) Discard partially filled syringes.
5) Collect 10 filled syringes.
6) Measure the volume in each of the syringes and document.
7) Add all of the syringe volumes together and divide by 10 to determine the calculated-measured volume. Document this number.
8) Prior to running the machine for usable syringes press the [**Measured Volume Keypad**] on the RUN Menu.
9) Enter the Calculated-Measured Volume
10) Press the [**SET**] button
11) Fill Volume will now be within closer tolerance to the selected fill volume.

CHAPTER 7– RUNNING

Introduction

After all previous installation and setup procedures have been completed the Smartfiller is almost ready to begin a production run of syringes. Prior to being able to run with optimal accuracy the operator must purge any air between the luer and the product bag. This can be done by performing a pre-run to clear air in the line and entering the measured volume. After the steps in the Pre-Run have been completed the Smartfiller is ready to fill syringes.

PRE-RUN

The pre-run is used to eliminate any air in the line going to the luer as well increase the accuracy of the fill volume.

1) Power on the Smartfiller®
2) Enter the SETUP Menu and adjust the following parameters for the desired application
   - Syringe Size
   - Reset Syringe Count
   - Fill Volume
   - Fill Rate
   - Suck Back
   - Batch Count
3) Load IV Bag and tubing set
4) Load Syringes (Minimum of 6 Syringes must loaded into Smartfiller® during Pre-Run for proper SETUP)
5) Enter Run Menu
6) Press [**START**] button
   - Smartfiller® will start filling process
   - Collect Syringes as they are pushed out of Star Wheel
7) Discard partially filled syringes
   - Apx. First 2-3 syringes
8) Use the remaining syringes to calculate the measured volume
   - (***Measured Volume*** in the Chapter 5)
9) Press Measured Volume Keypad button to bring up keypad
   - Enter the calculated measured volume
   - Press [**Set**] button
10) Machine is now ready for production run.

Production Run

1) Load Smartfiller® with Syringes

2) Go to the SETUP Menu and press [**RESET SYRINGE COUNT**]

3) Return the RUN Menu and check to ensure that the syringe count is at 0000

4) Press [**START**] button to resume filling process
   - The Smartfiller will then begin filling syringes. After the syringes are filled the Starwheel will index and discharge the syringes into syringe catch bin.

5) When batch is complete display will read "Machine Idle"

NOTE!

Syringe Filling Process can be paused/stopped at any time by pressing the STOP button. Smartfiller® will finish filling current syringe prior to coming to an idle state. Process can be resumed at anytime by pressing the START button.

WARNING!

DO NOT use the [**STOP**] button at any time for a means for servicing the machine. Never use the [**STOP**] button as a means for cleaning or servicing the machine. Always disconnect Power from the machine when operating around or near movable parts.

Duplicate Batch

Once the batch is complete the operator has the choice the leave the Smartfiller idle or the product materials may be removed. Operator should refer to company standard operating procedures for proper handling. If it is desired to leave the setup intact the operator may easily run another batch of syringes or different sized batch following the proceeding instructions.

1) Press [**SETUP**] to go to the SETUP Menu.
2) Press [**RESET SYRINGE COUNT**].
   - This will change the syringe count back to zero and allow the system to run another batch.
3) Return back to the RUN Menu and press [**START**] to begin the next batch.

NOTE

While in the SETUP Menu the operator may change the fill volume or other parameters that are desired. This may have a affect on the fill volume accuracy and it is recommended that the operator perform a complete setup and pre-run if changing parameters.

Changing Product

Changing the product that is to be drawn into the syringes must be done in an aseptic manner. If the user does not properly change the product there is possible risk of contamination.

NOTE

Manually clamp tubing set to prevent spillage.

1) If the machine is not currently powered on turn machine on.
2) Enter the RUN Menu
3) Press [**PURGE**]
   - This will clear the Smartfiller® of any empty or filled syringes.
4) Exit to Main Menu
5) Enter SETUP Menu
6) Press [**PINCH VALVE CLOSED**]
   - This will open the pinch valve so that the IV tubing set can be removed from the machine.
7) Disconnect fill adaptor from luer
8) Remove IV tubing set
9) Follow proper procedures for cleaning and sterilization of the Smartfiller®
10) Turn Smartfiller® Power On
11) Refer to Loading IV tubing section of manual.
12) Load new IV tubing into the Smartfiller®
13) Refer to SETUP section of manual and adjust settings as needed
14) User must complete PRE-Run instructions prior to filling usable syringes
15) Including Measured Volume

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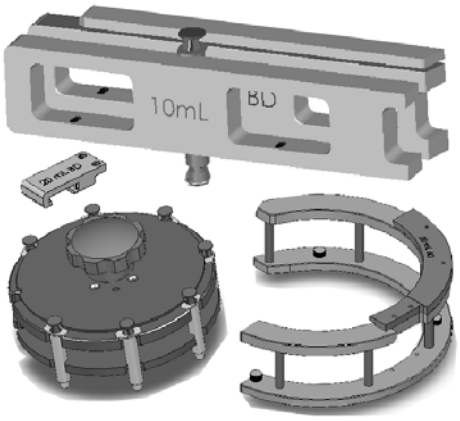
CHAPTER 8– SYSTEM CHANGEOVER

Introduction

The Smartfiller is capable of filling 8 different sizes of syringes. In order to change the size of syringe you will be filling the operator must change a few components as well. The changeover takes only a few minutes. Below are instructions on how to switch the components. The components can easily be identified for all changeover parts are engraved with the syringe size.



Removing Components

1) Unloosen the (4) knobs that hold the guide rails in place and remove guide rails.
2) Loosen the knob holding the Gripper Finger in place. Remove the Gripper Finger.
3) Loosen the thumb knobs on both the Stripper Finger and Stripper Wedge.
4) Rotate the Stripper wedge away from the Starwheel so that the Starwheel can be lifted up.
5) Loosen the Starwheel knob. Remove the Starwheel, when removing the Starwheel try to lift the wheel straight up off of the shaft without tilting it.
6) Loosen the (3) knobs that hold the Syringe Outer Guide in place. Remove the Syringe Outer Guide.

Installing NEW Components

1) Place the desired Starwheel onto the Starwheel shaft.

2) Place the knob back onto to Starwheel shaft. Make sure to tighten the knob firmly.

3) Place the appropriate Syringe Outer Guide Assembly onto its (3) post.

4) Replace the 3 knobs back onto the Syringe Outer Guide Assembly and tighten.

5) Place the appropriate Guide Rails and attach knobs to hold the rails or in place.

6) Align the Guide Rails by entering the Jog Menu on the touch screen and pressing the Starwheel Index button twice to ensure the Starwheel is in its home position.

7) Place 2 empty syringes in-between the guide rails so that the Flange is resting on each rail. Adjust the rails so that the syringe can move freely down the guide rails but not able to fall between them. Adjust the rails so that when the syringe is fed to the Starwheel it's centered with the slot in the wheel.

8) Rotate the Stripper Finger and Stripper Wedge into position.

9) Re-Position the Stripper Wedge so that syringes will be fed away from the Starwheel after being filled. When positioning the wedge make sure that the wedge will not force the syringe up against the Syringe Outer Guide Assembly.

10) Go to the SETUP Menu on the touchscreen. Change the syringe size to the appropriate size.

11) Re-Set the syringe count and enter batch count and fill settings.

NOTE

After changing syringe size, operator must re-enter all values in the setup menu prior to running the machine

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CHAPTER 9- SYSTEM MAINTENANCE

Introduction

Cleaning the Smartfiller should be done a daily basis in order to properly maintain the integrity and performance. This section of the manual is intended to provide the necessary procedures and guideline for establishing a good practice of preventive maintenance for the unit. Maintaining the equipment will provide the following benefits:

- Improve production by reducing machine downtime
- Mitigate wear and tear on equipment by keeping it clean and lubricated
- Detect potential machine/part failures early
- Avoid unexpected equipment failures that cause production loss
- Schedule full repairs instead of performing a partial repair
- Reduce maintenance and repair costs by eliminating emergency repair services

✋WARNING!

Smartfiller® maintenance shall not include any servicing of the unit. The only user required maintenance should be daily cleaning and removal of product. Mechanical and Electrical maintenance consist of many hazards that could cause possible serious injury to the user. If user has any doubt or concerns if the Smartfiller® unit is properly functioning, then proper notification should be made to the supplier of the Smartfiller® unit. Only trained personnel can service the Smartfiller® unit.

Maintaining and Cleaning the Smartfiller®

Cleaning the Smartfiller® should be done a daily basis in order to properly maintain the performance and integrity of the Smartfiller®.

WARNING!

Review Safety and Warning section of the manual prior to performing any of the below tasks. When removing movable parts use a tool such as forceps. ***DO NOT*** *attempt to remove by hand. Improper cleaning techniques of the Smartfiller® could result in personal injury.*

1) Remove the following from the Smartfiller® unit following previous instructions in the manual.
    - All syringes from Star Wheel
    - IV Tubing
2) Turn Power off to the Smartfiller®
3) Disconnect power cord from both the machine receptacle as well as the 110 VAC power receptacle
4) Remove the following parts from the Smartfiller® using forceps or tool.
    - Fill Adaptor
    - Luer Block
5) Tip-Cap Block
6) Disinfect and clean unit. Suggested disinfectant and cleaning agent is Isopropanol Alcohol.
7) Apply cleaning agent to a soft cloth.
8) Ensure that the cloth is not saturated with the cleaning agent.
9) Wipe all exterior surfaces of the Smartfiller® with the dampened soft cloth.
10) Visually inspect machine to check for any physical damage to the unit.

NOTE

DO NOT ***directly apply cleaning agent to the Smartfiller® unit***

WARNING!

DO NOT *attempt to clean inside of the power receptacle. Doing so increases risk of future fire or electrical shock.*

GLOSSARY OF TERMS

Term	Description
∅	Diameter
°C	Degrees Celsius
°F	Degrees Fahrenheit
AC	Alternating Current
ANSI	American National Standard Institute
AWG	American Wire Gauge
CD ROM	Compact Disc Read Only Memory
CD-RW	Compact Disc Read\Write
CE	Certificate of European Conformity (“Conformité Européene”)
cGMP	current Good Manufacturing Processes
CSV	Computer System Validation
DC	Direct Current
DS	Design Specification
DVD	Digital Versatile Disc
EHS	Environmental Health and Safety
FAT	Factory Acceptance Test
FDA	Food and Drug Administration (*United States)*
GAMP 4	Good Automation Manufacturing Practices
HMI	Human Machine Interface
I/O	Input / Output
IQ	Installation Qualification
ISO	International Organization of Standardization
LOTO	Lock out Tag out
NEMA	National Electrical Manufacturers Association
NFPA	National Fire Protection Association
OCR	Optical Character Recognition
OM	Operator’s Manual
OQ	Operational Qualification
PLC	Programmable Logic Controls
PQ	Performance Qualification
SS	Stainless Steel
SAT	Site Acceptance Test
SDLC	System Development Life Cycle
UL	Underwriters Laboratory
URS	User Requirement Specification
USDA	United States Department of Agriculture
VPM	Vials Per Minute
VPN	Virtual Private Network